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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,401	11/21/2005	Hiroshi Tsuchita	Q88294	1465

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
09/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/537,401	**Applicant(s)** TSUCHITA ET AL.	
	Examiner Marsha M. Tsay	**Art Unit** 1656	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 September 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,5,6,16,20 and 21*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Maryam Monshipouri/
Primary Examiner, Art Unit 1656

Continuation of 11. does NOT place the application in condition for allowance because: the reasons are the same as noted in the Office action of June 9, 2010. However, Applicants' after final remarks will be briefly addressed herein.

In their remarks, Applicants assert that (1) the legal precedent cited by the Examiner does not apply to the present case. Brantman clearly teaches, at col. 4 lines 8-12, that "the present invention employs carnitine to optimize skeletal muscle function in relation to oxidation of fatty acids for calories; to the oxidation of BAA for the effects summarized above; and to enhance the removal of toxic ammonia." Contrary to the Examiner's characterization that carnitine is not a desired component in the composition of Brantman, Brantman specifically requires the use of carnitine for its intended purpose. (2) Although Soop et al. teach that adequate muscle carnitine levels are maintained during exercise and that carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions, Soop et al.'s study relates to the single use of carnitine and its effect on skeletal muscle metabolism under normal physiological conditions. That is, the level of carnitine taught by Soop et al. might not be adequate for the purpose taught by Brantman (i.e. optimize skeletal muscle function, provides the best metabolic milieu, and maximize protein synthesis in skeletal muscle). (3) Third, the composition defined in the claims of the instant application is patentable over Brantman from the fact that the claimed composition retains and improves the desired function even camitine, which was an essential element of Brantman's composition, is omitted. The omission of an element and retention of its function is an indicia of unobviousness. In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966); MPEP 2144.04. (4) One of ordinary skill would recognize that according to Brantman, omission or exclusion of carnitine would markedly reduce desired physiological effects of the composition. Accordingly, one of ordinary skill in the art would not have prioritized the cost reduction effects at the cost of such physiological effects.

Applicants' arguments have been fully considered but they are not persuasive.

(1) Response: Applicants are reminded that the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." In re Sponnoble, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). Brantman discloses that carnitine is employed to optimize skeletal muscle function in relation to oxdiation of fatty acids for calories (col. 4 lines 8-13); however, Brantman also discloses that carnitine is synthesized in the body (col. 3 lines 59-60) and that it has the smallest amount in the composition (col. 4 lines 15-50). Therefore, since it was known in the art at the time of the invention that adequate muscle carnitine levels are maintained during exercise and that carnitine supplementation has no substantial effect on skeletal muscle metabolism under normal physiological conditions (Soop et al.), it would be reasonable for one of ordinary skill to exclude carnitine from said composition of Brantman since exogenous carnitine does not appear to have a substantial effect on skeletal muscle. Additionally, it would be reasonable for one of ordinary skill to know that excluding carnitine would save time and money because it is not absolutely required since there is endogenous carnitine present in the body.

(2) Response: As noted previously, Soop et al. disclose that adequate muscle carnitine levels are maintained during exercise, therefore, there would still be an appropriate level of carnitine present in the body when said composition of Brantman, without carnitine present, is administered during exercise, such that the branched amino acids will be oxidized and toxic ammonia will be removed.

(3) Response: The exclusion of carnitine from the composition of Brantman would still yield a composition that has the same function and properties as the instant composition which includes carnitine because as noted above, endogenous carnitine is produced in the body and maintained at an adequate level during exercise (Brantman, Soop et al.).

(4) Response: See the response of (2) and (3). Specifically, both Brantman and Soop et al. disclose that endogenous carnitine is produced in the body and Soop et al. further disclose that carnitine is maintained at an adequate level during exercise.

For at least these reasons, the 103(a) rejection is maintained.